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THE HIGH DOSE AND THE LOW DOSE FOOD IRRADIATION PROGRAM IN THE UNITED STATES

by

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Research & Development Command

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This document presents an overview of the wholesomeness testing of irradiated foods in the United States. The effect of irradiation on the wholesomeness aspects of the food has been researched more systematically and thoroughly than any other physical process. Many highly acceptable shelf-stable irradiated food items have been developed. The most extensive animal feeding/wholesomeness studies ever carried out on any food processing method continue to indicate that irradiated foods are wholesome.

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PREFACE

Preservation of food is a matter of vital importance. Many methods are being used such as the physical processes of drying, heating, freezing and irradiation, as well as the use of many chemical additives, such as antimicrobials (salt, nitrates), insecticides, and sprout inhibitors. All these methods cause chemical and physical changes. The beneficial effects are usually some easily observable technical factors. The potentials of detrimental effects are more difficult to assess. In case of chemical additives, the margin of safety is sometimes obtained by feeding to animals food containing 100 times the amount of additive proposed for use. In case of a physical preservation process, such as drying, heating, freezing and irradiation, such an approach is not feasible. The effect of irradiation on the wholesomeness aspects of the food has been researched more systematically and thoroughly than any other physical process. This report gives an overview of the wholesomeness testing of irradiated foods in the United States.

This report was presented by Dr. Ari Brynjolfsson at the International Symposium on Food Preservation by Irradiation, 21-25 November 1977, Wageningen, Netherlands.

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INTRODUCTION

Twenty-four years ago, on December 8, 1953, President Eisenhower made his plea for "Atoms for Peace". Addressing the General Assembly of the United Nations the President proposed a "way by which the miraculous inventiveness of man shall not be dedicated to his death, but consecrated to his life." To this end, he proposed the creation of an international agency, The International Atomic Energy Agency, to advance the peaceful uses of atomic energy.

On that occasion, Professor Niels Bohr, who had played a key role in the development of the atomic and nuclear sciences, and who had worked for free international flow of scientific information, gave my class at his Institute a day off after briefing us on the significance of the President's plea. He did this, he said, so we would remember.

"Atoms for Peace" opened a new horizon. In the food industry, the largest industry in the world, the tools of this new science were to help us breed new and better plants, help us understand better how plants utilize fertilizers, and help us preserve the food we had produced through our labor. With respect to food irradiation, we should recall U.S.Congressman Melvin Price's words in May of 1955: "I would like to suggest that we keep in mind what these developments could mean for the alleviation of food shortages in areas of the world which lack adequate modern transportation and refrigerated storage facilities."[1]

In the gloom of today's energy crunch, Congressman Price's words are more pertinent than ever before. Many of our preservation methods are energy demanding and are becoming increasingly expensive to maintain in the developed countries, and these methods are even more costly to introduce in the developing countries. This evolution of our technology foreshadows grave times, because the availability of food and the ability to preserve it and free it from pests and parasites are the prerequisites for good

[1] M. Price, Radiation Sterilization of Foods, Hearing Before the Sub-committee on Research and Development of the Joint Committee on Atomic Energy, Congress of the United States, (Government Printing Office), May 9 (1955).

health for every child and every adult and, therefore, basic to civilization. Food irradiation will not solve all our problems. Food irradiation will not replace the now widely used techniques of food processing, but it will add to the choices we have. Food irradiation will take its place when and where it can produce nutritionally superior products, when and where it can ease storage and distribution problems, when and where it can improve the public health by reducing the hazards of foodborne disease and when and where it is preferred by consumers because of lower cost and improved quality.

TWO PROBLEMS FOR FOOD IRRADIATION

Irradiation: An additive or a process?

The U.S. Food Additive Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act defines food irradiation as an additive and "deems intentionally irradiated foods to be adulterated unless such use of irradiation has been cleared for safety by regulation."[2]

It was reasonable for U.S. legislators in 1958 to define food irradiation as an additive since the question of induced activity in irradiated foods had not been resolved. At that time, serious consideration was being given to the use of high energy (24 MeV) radiation potentially able to transform nuclei and produce radioactivity. The radiation now proposed for use neither induces radioactivity nor transforms nuclei. Its use can be considered a physical process. The administrators of the law continue, however, to follow procedures valid if irradiation of food is considered an additive, rather than a process.

Radiation and the public

Radiation is used beneficially in many fields. It is used in the medical field to diagnose and treat cancer, it is used extensively to sterilize medical equipment, it is used to polymerize and crosslink plastic,

[2] Federal Food, Drug and Cosmetic Act as amended, 21 U.S. Code 321, 21 Code of Federal Regulations, Part 121 - Food Additives.

and it is used to cure paints and many other items. More publicized, however, are the harmful effects. The word radiation conjures up thoughts of atomic bombs, fallout, cancer, and genetic defects. The public (including many scientists) fails to distinguish between radiation effects on living things and on food. For this reason, it is rather easy to excite the public and make headlines with experiments showing detrimental effects even if the experiments are of little relevance or are based on erroneous treatment of the data. Well-established business enterprises and public institutions are sometimes reluctant to risk investment in radiation processes even when considerable business advantage or public benefit would be derived from the use of radiation.

WHO SHOULD DEVELOP FOOD IRRADIATION AND PROVE WHOLESOMENESS?

Traditionally, the American free enterprise system researches and develops food processing and preservation methods. Animal testing for clearing a simple chemical compound as an additive to food is manageable by industry. But the "additive" *food irradiation* evades identification. We can search and search for 20 years without finding any harmful effects, and then be told that maybe we did not search in the right place, that maybe we did not look in the right way, that maybe we did not look hard enough, that maybe carrot cells that grew normally in neither heat-sterilized nor irradiated sugar solutions were an indication that irradiated meats were unsafe. The extent of testing required to obtain Food and Drug Administration (FDA) clearances has become difficult to predict. A clearance is not a license for a single person or a single company to preserve its own product. All who comply with the regulation are authorized to use the process. A company investing in the work needed to obtain clearance would not necessarily have a competitive advantage. For these reasons and for those mentioned in section 2 above, the American food industry shuns expenditures for obtaining FDA approval. After all, industry does not need irradiated food. Business concerns itself largely with the distribution of market shares.

Business is concerned primarily with profit. If food irradiation is to be exploited for the benefit of all people, public expenditures are needed to clear the food, government controls must be minimized, and free flow in the distribution of food must be facilitated through international acceptances.

In the U.S.A. the National Academy of Sciences Advisory Committee recommended on May 27, 1953, that the Department of the Army take on the task to: "correlate and support research in this field." The Department of the

Army was probably recommended because, during World War II, it had acquired significant capabilities in food processing and technology research and development. The Army food and nutrition laboratories cooperated closely with other agencies of the Government and, in particular, with the Atomic Energy Commission (AEC), which supplied radiation sources and radiation technology. The National Food Irradiation Program was monitored by the Subcommittee on Research and Development of the Joint Committee on Atomic Energy, Congress of the United States. In the sixties, AEC activities in the food irradiation program went well beyond assistance in source development and irradiation technology in that AEC had the responsibility for all low dose (<10 kGy) applications. Since 1970, AEC activity has been limited to its support of the International Food Irradiation Project. The National Food Irradiation Program conducted by the Department of the Army continues, as it did in the fifties, to be oriented toward national needs including civilian needs. Presently, its mission is to develop food irradiation technology, to establish the wholesomeness of radappertized meats and poultry, and to eventually transfer the technology to private industry.

THE COMPONENTS OF PRESERVATION

If not preserved, food will spoil, lose its nutritional quality, become toxic and inedible. Food must be preserved to store it in times of abundance for use in times of shortage, and to make possible its transportation from areas of surplus to areas of scarcity. The ability to preserve food is at the root of the evolution of civilization. In early history, the principal crops were wheat and barley that when dried, could easily be stored and transported. Sheep and other animals which could be slaughtered when needed served as another method of storing food.

Human history has taught us to select from nature foods that are reasonably adequate nutritionally, fairly free from toxins, and do not cause much cancer, genetic effects, birth defects or other anomalies that could seriously limit survival and reproduction. Scrupulous observation and Darwinian selection have taught us sophistication in these matters. We must require that any food preservation method retain these qualities. We, therefore, require that:

a. Nutritional quality be retained.

b. The food is free of pathogenic and spoilage organisms and their toxins.

c. The food is free of chemical compounds causing:

(1) Toxic effects
(2) Cancer
(3) Genetic changes
(4) Birth defects.

RETENTION OF NUTRITION AND FREEDOM FROM PATHOGENS

In the early days spoilage by microorganisms and insects was usually the major factor limiting storage stability of food. But, there is much more to preservation. Food free of microorganisms will often break down because of enzymatic and oxidative reactions. While radiation is very effective in killing microorganisms, it causes only minor chemical changes so autolytic and proteolytic enzymes are left fairly intact even at high doses. To obtain the greatest retention and stability of nutrients, it is usually preferable to use a combination of irradiation and mild heat treatment (70°C), drying, refrigeration, or freezing. In addition, it is often important to inhibit or prevent oxidative reactions. This may be done by packaging under vacuum. The technology for stabilizing meats this way is steadily being improved at our laboratory and has resulted in many meat items that retain their nutritional quality, are stable at room temperature for extended periods of time, and are completely free of pathogens. This work has been described elsewhere.[3-9]

[3] E.S. Josephson, A. Brynjolfsson, E. Wierbicki, D.B. Rowley, C. Merritt, Jr., R.W. Baker, J.J. Kolloran, H.T. Thomas, Radappertization of meat, meat products, and poultry; Radiation Preservation of Food (Proc. of Symposium Bombay 1972) IAEA, Vienna, p. 471 (1973).

[4] E.S. Josephson, A. Brynjolfsson, E. Wierbicki, The use of ionizing radiation for preservation of food and feed products; Radiation Research (Acad. Press, N.Y., San Francisco, London) p. 96 (1975).

[5] E. Wierbicki, A. Brynjolfsson, H.C. Johnson, D.B. Rowley, Preservation of meats by ionizing radiation - an update; Rapporteurs Papers (Proc. of the 21st European Meeting of Meat Research Workers, Berne 31 August 1975).

[6] A. Anellis, D.B. Rowley, E.W. Ross, Jr., Microbiological safety of radappertized beef. Proc. of the First Int. Congress on Engineering and Food, Boston, MA, August 1976. To be published by Arlington Publ. Co., Chicago.

WHOLESOMENESS

After developing technology that retains nutrition and eliminates pathogens, the food must be tested for chemical compounds causing toxic effects, cancer, genetic changes, and birth defects.

The first phase was to carry out short term toxicological studies using animals. No toxic effects whatsoever were found using the animal species.

TABLE 1. List of 54 Foods Tested on Humans/in the Short-Term Toxicological Studies

11 Meat Items

Bacon	Chicken stew
Corned beef	Frankfurters
Ground beef	Ground ham
Beef steak	Ham steak
Chicken	Ground pork
	Sausage

5 Fish Items

Cod	Salmon
Haddock	Shrimp
	Tuna

9 Fruit Items

Dried apricots	Oranges
Cherries	Orange juice
Dried fruit compote	Peaches
Melon balls	Dried pears
	Strawberries

[7] F. Heiligman, E. Wierbicki, J.S. Cohen, V.C. Mason, Industrial production and quality of whole carcass beef rolls used in the wholesomeness testing of radappertized beef, ibid.

[8] J.J. Killoran, J.J. Howker, E. Wierbicki, Reliability of the tinplate can for packaging of radappertized beef under production conditions, ibid.

[9] J.J. Killoran, J.S. Cohen, E. Wierbicki, Reliability of flexible packaging of radappertized beef under production conditions, ibid.

TABLE 1. List of 54 Foods Tested on Humans/in the Short-Term Toxicological Studies (Cont'd)

14 Vegetable Items

Asparagus	Cauliflower
Green beans	Celery
Lima beans	Cole slaw
Beets	Mushrooms
Brussel sprouts	Peas
Cabbage	Sweet potatoes
Carrots	White potatoes

9 Cereal Product Items

Bread	Macaroni
Crackers	Nut roll
Cereal bar	Pound cake
Flour	Rice
	Corn

6 Miscellaneous Items

Dessert powder	Pineapple jam
Powdered whole milk	Strawberry jam
Peanut butter	Sugar

The second phase was short-term feeding studies on humans. Using human volunteers, 54 food items listed in Table 1 were tested in the years 1955-1959. Seven 15-day tests were conducted. The caloric intake of irradiated foods was 32% to 100%. A thorough medical examination of the subjects was made. This included clinical examination, as well as measurements of various physiological and biochemical parameters. In no case were there any indications of toxicity due to the consumption of irradiated foods.

The third phase was long-term animal feeding studies to check the toxicity and the nutritional quality of the 22 representative irradiated foods listed in Table 2.

TABLE 2. List of 22 Foods Tested in Long-Term Toxicological Studies during the 1956 - 1965 Period

8 Animal Products	
Ground beef	Pork loin
Beef stew	Bacon
Chicken	Dried eggs
Chicken stew	Evaporated milk
3 Sea Food Items	
Cod fish	Shrimp
Tuna	
5 Vegetable Items	
Green beans	White potatoes
Cabbage	Sweet potatoes
Carrots	
4 Fruits	
Fruit compote	Peaches
Pineapple jam	Oranges
2 Cereals	
Flour	Corn

The aim of the long-term feeding studies was to clear food irradiation as a process. They were of unparalleled scope and magnitude. Never before had any food processing method been tested so thoroughly. The protocols were made by consulting extensively with a great many specialists from the National Research Council and the FDA. FDA scientists were frequently informed and counselled. In 1965 the Surgeon General's scientists concluded that:

> "Food irradiated up to absorbed doses of 5.6 megarads with Co-60 source of gamma radiation or with electrons with energies up to 10 million electron volts have been found to be wholesome; i.e. safe, and nutritionally adequate."[10]

[10] Statement on the wholesomeness of irradiated foods by the Surgeon General, Department of the Army; Radiation Processing of Foods, Hearings Before the Subcommittee on Research and Development and Radiation of the Joint Committee on Atomic Energy, Congress of the United States, June 9 and 10, p. 105 (1965).

The design of the studies was aimed at obtaining a broad clearance for the food irradiation process. No toxicity was demonstrated in any of the 22 items.

About the time the studies were completed and the above conclusion was reached, the requirements for testing were changed partly because of the Food Additive Amendment of 1958, and partly because of thalidomide, which despite approval in several countries, was discovered to affect normal fetal growth and result in abnormally shortened limbs in the newborn.

The thalidomide incident was completely unrelated to irradiated foods, but public outrage nonetheless called for greater caution in all clearances. A ham petition was submitted on August 24, 1966, but was withdrawn July 3, 1968, because the testing was considered inadequate under the new guidelines. The testing had been conducted with pork and bacon.

A protocol for new long-term toxicological studies on meats was designed. Because ham contained nitrites which were by then suspect, it was decided to test beef as the first meat item in renewed wholesomeness testing. A contract was awarded in March, 1971, and the contractor started feeding animals in the fall of 1971. The protocol for these studies is outlined by Johnson et al.[11] This study has now been completed, but the contractor has failed to submit a final report and has still not evaluated all the histopathological data. Review of quarterly reports has not revealed any anomalies and there is no indication that the irradiated products are inferior to the control groups.

In March 1975, the animal feeding studies on beef were proceeding well. A decision was, therefore, made to initiate animal feeding studies on chicken, pork, and ham. The protocols were similar to the protocol for beef. The major facets of these studies are outlined in Tables 3-9.

[11] H.C. Johnson, N. Raica, R.W. Baker, "The Wholesomeness testing of radappertized enzyme-inactivated beef - a progress report", Proc. 4th Int. Congress Food Technology, Madrid, 1974 (to be published).

TABLE 3. <u>Key Features of the Toxicity and Carcinogenicity Studies on Radappertized Beef</u>

A. Each group consisted of:

1. 30 Dogs
2. 140 Rats
3. 150 Mice

B. Five diets were studied:

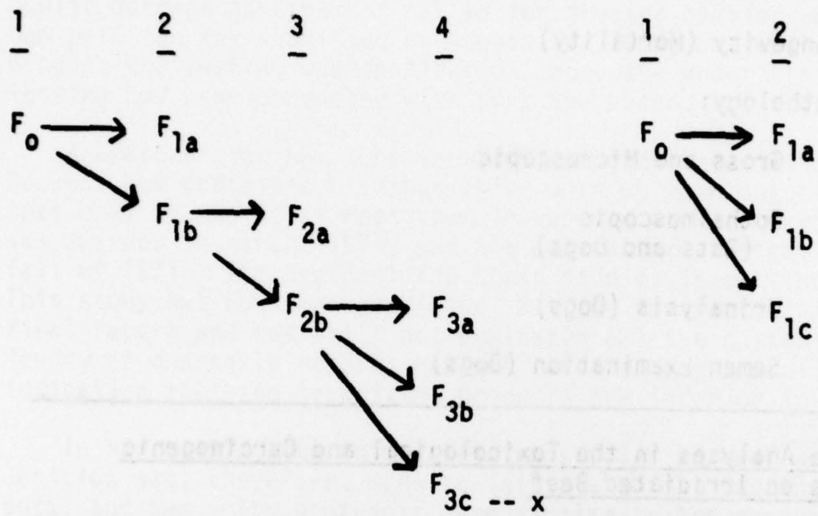
1. 100% Basal Diet (CGN)
2. 35% Enzyme-Inactivated Beef, Stored Frozen (CGF)
3. 35% Thermally Sterilized Beef (F_o = 5.8) (CGT)
4. 35% Gamma Ray Radappertized Beef (TGCO)
5. 35% Electron Radappertized Beef (TGEL)

C. Comparisons:

1. CGN - Husbandry and Management Indicator
2. CGF and CGT <u>vs.</u> TGCO and TGEL

TABLE 4. <u>Breeding Program and Generations in the Toxicological and Carcinogenic Studies on Radappertized beef</u> [a]

Rodent Generations [b] Dog Generations [c]



a F_o Generation is derived from stock animals fed the respective diets prior to conception and through weaning of the F_o Generation.

b F_o Generation maintained on study for 2 years.

c F_o Generation maintained on study for 3 years.

TABLE 5. General Parameters of the Toxicological and Carcinogenic Studies on Irradiated Beef

Growth and Body Weight
Food Consumption
Reproduction Performance
Longevity (Mortality)
Pathology:
Gross and Microscopic
Opthalmoscopic (Rats and Dogs)
Urinalysis (Dogs)
Semen Examination (Dogs)

TABLE 6. Routine Analyses in the Toxicological and Carcinogenic Studies on Irradiated Beef

Hematology and Chemistry

Total and Differential Cell Counts
Hemoglobin ahd Hematocrit
Serum Protein, Albumin and Globulin
Prothrombin Time, SGOT, SGPT
Serum Alkaline Phosphatase (Dogs)
Serum Creatinine (Dogs)
BSP Liver Function (Dogs)

Diets

Thiamine	Riboflavin
Pyridoxine	Niacin
Ascorbic Acid	Vitamin A
Vitamin E	
Fatty Acids	Amino Acids
Calcium	Phosphorus

Proximate (Protein, Fat, Ash, Moisture)
Peroxide Number, TBA, pH

TABLE 7. Teratogenic and Mutagenic Studies in the Wholesomeness Testing of Radappertized Beef

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Teratogenic Studies In:

1. Albino Mice
2. Albino Rats
3. Golden Syrian Hamsters
4. Albino Rabbits

Mutagenic Studies

1. Host-Mediated Assay and Ames Test
2. Sex-Linked Recessive Test in Drosophila
3. Dominant Lethal Studies in Rats and Mice
4. Cytogenic Analyses for Chromosome Abnormalities
    a. Micro-Nucleus Test
    b. Canine Lymphocytes
    c. Rodent Bone Marrow

TABLE 8. Status of the Beef Wholesomeness Studies (March, 1976)

1.	The 12-D Dose Determined (4.1 Mrad).
2.	No Induced Radioactivity Measured.
3.	Nutritional Studies, Including Anti-Metabolite Studies, are Continuing.
4.	Analysis of Volatile Compounds are Continuing.
5.	Teratogenicity Studies Completed.
6.	Mutagenic Studies Initiated.
7.	Toxicological and Carcinogenic Studies are Continuing.

TABLE 9. Major Differences in Protocols for Radappertized Chicken, Pork and Ham from the Protocol for Radappertized Beef

Mutagenic Studies

1. Delete micronucleus test and host mediated assay
2. Add:
   a. Cytogenic analysis of testicular cells from males in dominant lethal studies.
   b. Heritable translocation test with mice.

Toxicological and Carcinogenic Studies

1. Increase in nutrients and pesticides analyzed.
2. Same diet groups, but use NIH open formula ration for rodents.
3. Data oriented to specific dam of stock generation.
4. Comparisons are frozen vs. thermal and gamma and electron.
5. Increase Frozen Control Group by 50%.

The contracts were let in May 1976, and animals were on the study by the end of the year. The contractor for chicken has done well, and the studies are proceeding on schedule. The contractor that had both the contract for pork and the contract for the ham has failed to manage the contract work properly and the studies must be reinitiated.

EXTRAPOLATION AND INTERPOLATION OF WHOLESOMENESS STUDIES

The studies on beef, chicken, and pork represent the major meat items; the study on ham represents a cured item; and the pork contains 0.1% white pepper. At the conclusion of these studies, the intent is to seek clearance for irradiation processing of all meat items; that is, we intend to seek clearance for radappertization of meats as a process. To this end, we are conducting extensive studies on the radiation chemistry of the meats and the different components of meats. These studies, which will be discussed by Dr. Taub [12] and Dr. Merritt [13] at this Symposium, will be used not only to support the validity of extrapolation and interpolation, but the studies should also support the wholesomeness evaluation of the animal feeding studies.

All the radiolytic products detected in the volatiles from beef have been evaluated for toxicity by the Select Committee on Health Aspects of Irradiated Beef under the Life Sciences Research Office, Federation of American Societies for Experimental Biology. The final report has been received.[14] Sixty-five

[12] I.A. Taub, R.A. Kaprielian, J.W. Halliday, "Radiation chemistry of high protein foods irradiated at low temperatures", these Proceedings, Paper IAEA-SM-221/59.

[13] C. Merritt, Jr., P. Angelini, W.W. Nawar, "Chemical analysis of radiolysis products relating to the wholesomeness of irradiated food", these Proceedings, Paper IAEA-SM-222/51.

[14] Report of the Select Committee on Health Aspects of Irradiated Beef, Life Sciences Research Office, Federation of American Societies for Experimental Biology. Contract No. DAMD-17-76-C-6055, National Technical Information Services, Springfield, Virginia 22161 (1977).

compounds had been identified in irradiated beef by Dr. Merritt et al.[13] The Committee concluded that there were no grounds to suspect that the radiolytic compounds evaluated in the report would constitute any hazard to health to persons consuming reasonable quantities of beef irradiated in the described manner.

LOW DOSE PROGRAM

The Interdepartmental Committee on Radiation Preservation of Food has had four groups of experts study and review the perspective of food irradiation in the United States and to outline future effort. These panels of experts were to clarify problems with present processing, storage and distribution; discuss alternative problems, and estimate additional work that needs to be done. The four panels, one on fruit and vegetables, another on fish and fish products, third on poultry and poultry products, and the fourth on red meats and meat products, have had several meetings. The final reports to the Interdepartmental Committee on Radiation Preservation of Food from each of the four panels were received in March 1978.

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